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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,811	09/14/2006	Chikara Ohyama	Q74728	1462
23373	7590	09/28/2010	EXAMINER	
SUGHRUE MION, PLLC			HARRIS, ALANA M	
2100 PENNSYLVANIA AVENUE, N.W.				
SUITE 800			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20037			1643	
NOTIFICATION DATE		DELIVERY MODE		
09/28/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/549,811	<b>Applicant(s)</b> OHYAMA ET AL.
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09/07/2010.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.  
 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 and 14-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 7, 2010 has been entered.

2. Claims 1-7 and 11-23 are pending.

Claims 11-13, drawn to non-elected inventions and are not examined on the merits.

Claims 1, 6 and 17 have been amended.

Claims 1-7 and 14-23 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 1-6 and 14-23 under 35 U.S.C. 102(b) as being anticipated by Fukuda et al./U.S. Patent number 6,136,580 (issued October 24, 2000) is withdrawn in light of Applicants' arguments presented in the Remarks submitted September 7, 2010.

***New Grounds of Objection***

***Specification***

5. The disclosure is objected to because of the following informality: in the "Brief Description of the Drawings" Figure 3 is found on page 4, however in the actual drawings there is Figure 3A and Figure 3B. Applicants should have a corresponding caption for each figure. Correction is required.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al./U.S. Patent number 6,136,580 (issued October 24, 2000), and further in view of VanderElst et al. (*Glycobiology* 8(7): 731-740, 1998). In anticipation of an obviousness rejection Applicants assert “[t]he pending claims are directed to a new use for antibody that detects C2-GnT polypeptides”, see Remarks, bridging pages 7 and 8. Applicants further assert Fukuda merely discloses an antibody against C2-GnT-M and this in and of itself does not read on the claimed inventive methods. Applicants’ points of view and arguments have been carefully considered but fail to persuade.

Fukuda teaches a method of detecting mammalian polypeptide core 2, core 4 and I branching  $\beta$ 1,6-N-acetylglucosaminyltransferase (C2GnT-M) in various samples using immunological procedures, wherein the samples may be any biological fluid, cell, tissue or specimen obtained by biopsy, see column 7, lines 5-15; and column 15, lines 31-42. Fukuda reads on comparing samples including a control and increased risks, see page 11, lines 36-45. It is clear

from the amended claims that if a higher level of core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase protein is more than that of the normal sample, a high possibility of cancer recurrence is imminent. Hence, Fukuda intrinsically teaches increased C2GnT-M expressin in a sample is indicative of high possibility of cancer recurrence. “[D]etecting the possiblity of cancer recurrence...” cited in amended claims 1 and 17 seem to be based on assessing the level of C2  $\beta$  1,6-N-acetylglucosaminyltransferase and comparing levels between samples, which Fukuda has done. Fukuda does not teach the claimed method wherein, the immunologically assessed sample is cancer cells, particularly prostate or testicular tumor cancer.

However, Fukuda does teach assays, wherein cancer cells and samples from testis and prostate tissues are assayed, see Figure 8; and column 20, Example IV. Moreover, VanderElst teaches assaying  $\beta$ 1,6 N-acetylglucosaminyltransferase (core 2 GlcNac-T) protein expression in tissue lysates including a lysate from testis, see Figure 2(A) on page 733. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of all the references because they both note assessing cancer samples from prostate and bladder and control cells for C2GnT expression, see all documents in their entirety. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both references, immunological detection of C2GnT in samples is easily determined.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works *a flexible schedule*, however she can normally be reached Monday through Saturday on 8 am to 8 pm with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Alana M. Harris, Ph.D.  
23 September 2010  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643